

First Regular Session
Seventy-third General Assembly
STATE OF COLORADO

DRAFT
1.15.21

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LLS NO. 21-0091.01 Richard Sweetman x4333

SENATE BILL

SENATE SPONSORSHIP

Ginal,

HOUSE SPONSORSHIP

(None),

BILL TOPIC: "Expand Canadian Rx Import Program"
DEADLINES: Finalize by: JAN 19, 2021 File by: JAN 22, 2021

A BILL FOR AN ACT

101 CONCERNING EXPANDING THE CANADIAN PRESCRIPTION DRUG
102 IMPORTATION PROGRAM TO INCLUDE PRESCRIPTION DRUG
103 SUPPLIERS FROM NATIONS OTHER THAN CANADA UPON THE
104 ENACTMENT OF LEGISLATION BY THE UNITED STATES CONGRESS
105 AUTHORIZING SUCH PRACTICE.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

In 2019, the Colorado general assembly enacted, and the governor subsequently signed into law, the Canadian prescription drug importation

*Capital letters or bold & italic numbers indicate new material to be added to existing statute.
Dashes through the words indicate deletions from existing statute.*

program (program) in the department of health care policy and financing (department). The bill states that the department may expand the program to allow a manufacturer, wholesale distributor, or pharmacy from a nation other than Canada to export prescription drugs into the state under the program if certain conditions are met.

If, upon the satisfaction of these conditions, the department decides to expand the program, the executive director of the department shall notify the president of the senate, the speaker of the house of representatives, and specified legislative committees, of the department's intent to do so. The executive director shall provide the notice at least 30 days before the program is expanded, and the notice may include any recommendations of the department for legislation to amend the program to reflect its expansion.

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1. Legislative declaration.** (1) The general assembly
3 finds that:

4 (a) The people of the United States pay the highest prescription
5 drug prices in the world, to the detriment of Colorado consumers,
6 employers, and the state;

7 (b) The cost of prescription drugs continues to rise faster than any
8 other major component of health care, contributing to the affordability
9 challenge faced by Colorado consumers, employers, and the state;

10 (c) Given the COVID-19 pandemic and the resulting economic
11 downturn, the affordability of prescription drugs is more important than
12 ever in the state of Colorado;

13 (d) In 2019, the general assembly enacted, and the governor
14 subsequently signed into law, Senate Bill 19-005, which created the
15 Canadian prescription drug importation program in the department of
16 health care policy and financing, which program requires the department,
17 upon approval of the program by the United States secretary of health and
18 human services, to access lower-priced prescription drugs in Canada; and

1 (e) Many other countries have even lower prescription drug prices
2 than Canada, as well as different supplies of specific drugs.

3 (2) Therefore, the general assembly declares that by accessing
4 additional countries' drug supplies through Colorado's drug importation
5 program, Colorado could even further increase access and cost savings
6 associated with the program.

7 **SECTION 2.** In Colorado Revised Statutes, **add** 25.5-2.5-208 as
8 follows:

9 **25.5-2.5-208. Expansion of program to include additional**
10 **foreign suppliers - federal action required - notice to general**
11 **assembly.** (1) NOTWITHSTANDING ANY PROVISION OF THIS PART 2 TO THE
12 CONTRARY, THE STATE DEPARTMENT MAY EXPAND THE PROGRAM TO
13 ALLOW A MANUFACTURER, WHOLESALE DISTRIBUTOR, OR PHARMACY
14 FROM A NATION OTHER THAN CANADA TO EXPORT PRESCRIPTION DRUGS
15 INTO THE STATE UNDER THE PROGRAM IF:

16 (a) THE UNITED STATES CONGRESS ENACTS LEGISLATION TO
17 AMEND 21 U.S.C. SEC. 384 OR OTHERWISE ENACTS LEGISLATION TO
18 PERMIT STATES, INCLUDING COLORADO, TO IMPORT PRESCRIPTION DRUGS
19 FROM FOREIGN COUNTRIES OTHER THAN CANADA;

20 (b) A VENDOR, IN CONSULTATION WITH THE STATE DEPARTMENT,
21 HAS IDENTIFIED THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR
22 PHARMACY AS A SUPPLIER THAT SATISFIES THE REQUIREMENTS OF THE
23 PROGRAM AND THAT WILL EXPORT PRESCRIPTION DRUGS AT PRICES THAT
24 WILL PROVIDE COST SAVINGS TO THE STATE;

25 (c) THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR
26 PHARMACY IS APPROPRIATELY LICENSED OR PERMITTED UNDER THAT
27 NATION'S LAWS AND REGULATIONS PERTAINING TO THE MANUFACTURING,

1 DISTRIBUTION, OR DISPENSING OF PRESCRIPTION DRUGS;

2 (d) THE MANUFACTURER, WHOLESALE DISTRIBUTOR, OR
3 PHARMACY IS LOCATED IN A NATION THAT IS APPROVED TO EXPORT
4 PRESCRIPTION DRUGS INTO COLORADO BY THE UNITED STATES
5 SECRETARY OF HEALTH AND HUMAN SERVICES OR BY ANOTHER
6 AUTHORITY THAT IS DESIGNATED FOR SUCH PURPOSE BY FEDERAL LAW;
7 AND

8 (e) THE STATE DEPARTMENT SUBMITS EVIDENCE TO THE PRESIDENT
9 OF THE SENATE, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AND
10 THE HEALTH AND HUMAN SERVICES COMMITTEE OF THE SENATE AND THE
11 HEALTH AND INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES,
12 OR ANY SUCCESSOR COMMITTEES, WHICH EVIDENCE COMPARES THE
13 EXPORTING NATION'S REGULATORY SYSTEM FOR PRESCRIPTION DRUGS TO
14 THE REGULATORY SYSTEM FOR PRESCRIPTION DRUGS ADMINISTERED BY
15 THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO THE
16 FEDERAL ACT AND DEMONSTRATES THAT THE EXPORTING NATION'S
17 REGULATORY SYSTEM IS AS STRINGENT AS THE SYSTEM IN THE UNITED
18 STATES OR OTHERWISE ENSURES THE SAFETY, PURITY, AND POTENCY OF
19 THE PRESCRIPTION DRUGS FROM THE EXPORTING NATION. THE EVIDENCE
20 MUST COMPARE THE REGULATIONS FOR:

21 (I) SECURING THE SUPPLY CHAIN FOR PRESCRIPTION DRUGS;

22 (II) PRESCRIPTION DRUG MANUFACTURING;

23 (III) PRESCRIPTION DRUG LABELING; AND

24 (IV) PRESCRIPTION DRUG TRACKING AND TRACING.

25 (2) IF, UPON THE SATISFACTION OF THE CONDITIONS DESCRIBED IN
26 SUBSECTION (1) OF THIS SECTION, THE STATE DEPARTMENT DECIDES TO
27 EXPAND THE PROGRAM TO ALLOW A MANUFACTURER, WHOLESALE

1 DISTRIBUTOR, OR PHARMACY FROM A NATION OTHER THAN CANADA TO
2 EXPORT PRESCRIPTION DRUGS INTO THE STATE UNDER THE PROGRAM, THE
3 EXECUTIVE DIRECTOR SHALL NOTIFY THE PRESIDENT OF THE SENATE, THE
4 SPEAKER OF THE HOUSE OF REPRESENTATIVES, AND THE HEALTH AND
5 HUMAN SERVICES COMMITTEE OF THE SENATE AND THE HEALTH AND
6 INSURANCE COMMITTEE OF THE HOUSE OF REPRESENTATIVES, OR ANY
7 SUCCESSOR COMMITTEES, OF THE STATE DEPARTMENT'S INTENT TO DO SO.
8 THE EXECUTIVE DIRECTOR SHALL PROVIDE THE NOTICE AT LEAST THIRTY
9 DAYS BEFORE THE PROGRAM IS EXPANDED, AND THE NOTICE MAY INCLUDE
10 ANY RECOMMENDATIONS OF THE STATE DEPARTMENT FOR LEGISLATION TO
11 AMEND THIS PART 2 TO REFLECT THE EXPANSION OF THE PROGRAM.

12 (3) IF THE STATE DEPARTMENT EXPANDS THE PROGRAM IN
13 ACCORDANCE WITH THIS SECTION, AN ELIGIBLE IMPORTER MAY IMPORT A
14 PRESCRIPTION DRUG FROM A FOREIGN SUPPLIER PURSUANT TO THIS
15 SECTION IF THE DRUG THAT IS TO BE IMPORTED IS A PRESCRIPTION DRUG,
16 AS DEFINED IN 21 U.S.C. SEC. 384 (a)(3).

17 **SECTION 3. Act subject to petition - effective date.** This act
18 takes effect at 12:01 a.m. on the day following the expiration of the
19 ninety-day period after final adjournment of the general assembly; except
20 that, if a referendum petition is filed pursuant to section 1 (3) of article V
21 of the state constitution against this act or an item, section, or part of this
22 act within such period, then the act, item, section, or part will not take
23 effect unless approved by the people at the general election to be held in
24 November 2022 and, in such case, will take effect on the date of the
25 official declaration of the vote thereon by the governor.